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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/044,683	01/08/2002	William John Martin		9709

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EXAMINER	
FOLEY, SHANON A	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 11/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/044,683	MARTIN, WILLIAM JOHN	
	Examiner	Art Unit	
	Shanon Foley	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 July 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) *1-18* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *19-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of group IX in the reply filed on July 23, 2004 is acknowledged.

Claims 1-18 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected subject matter, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on July 23, 2004.

Information Disclosure Statement

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Specification

The abstract of the disclosure is objected to because it can be no longer than 150 words. Correction is required. See MPEP § 608.01(b).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 19-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 19 and 20 require that the subject is exposed to a form of energy that causes morphological and/or functional cell damage to stealth virus cultured cells, but does not cause this same damage to uninfected cells. It is not clear from the claim language how exposing a subject to a certain energy would effect cells in a culture dish. It is also not clear how cells affected in culture would be seen as treating an infected subject since the subject does not appear to be affected by the treatment from the claims.

The limitations intended to be encompassed by claims 20 and 21 cannot be determined because the claims depend from a non-elected claim that is not under consideration. It is presumed that these claims are intended to depend from claim 19 and will be treated as such in the interest of compact prosecution. However, this treatment does not relieve applicant from the burden of remedying this rejection.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 19-21 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a credible asserted utility or a well established utility.

An asserted credible utility is assessed from the standpoint of whether a person of ordinary skill in the art would accept that the disclosed invention is currently available for such use.

In the instant case, the claims are drawn to a method of treating a subject with a stealth virus infection by exposing the subject to a form of energy that causes morphological and/or functional cell damage to stealth virus cultured cells, but does not cause this same damage to uninfected cells. It is not clear from the claims 19 or 20 how exposing a subject to a certain energy would effect cells in a culture dish. It is also not clear how cells affected in culture would be seen as treating an infected subject since the subject does not appear to be affected by the treatment from the claims. Claim 21 specifies that infected cells within the patient are affected by the treatment.

There is no clear definition provided in the disclosure of what a stealth virus is. On page 6, the disclosure states that a stealth virus belong to a group of atypically structured, non-inflammatory viruses. The disclosure also asserts an association between stealth virus infection with various infections, psychiatric illnesses and cancer. However, on page 21, the specification states that stealth viruses do not induce inflammatory, cell death or an immune reaction. On pages 29-30, the disclosure states that stealth viruses have the capability of adopting and mutating genes from other viral, bacterial and cellular origins. Therefore, it is not clear how these stealth virus infected patients were/are identified. However, the specification further describes stealth viruses as infectious agents that induce a characteristic vacuolating cytopathic effect (CPE) in culture cells. However, this phenomenon does not aid in clearly identifying characteristics of the virus to one of ordinary skill in the art. To illustrate this point, the teachings of Sahagun-Ruiz et al. (Virus Genes. 2004; 28 (1): 71-83) is cited. Sahagun-Ruiz et al. describe five open reading frames (ORFs) that were sequenced from a prototype stealth virus. Sahagun-Ruiz et al. describe this virus as a "heterogeneous group of atypically structured

putative viruses that have been isolated from patients..." (emphasis added). Sahagun-Ruiz et al. further state that "[t]he biological significance of this entity is not yet clear, and it has not been independently replicated in tissue culture. "Stealth virus" sequences submitted to Genbank include sequences also reported in African Green Monkey Simian Cytomegalovirus, bacterial, fungal and human genomes." See the first full paragraph of the second column on page 72 of Sahagun-Ruiz et al. From the discussion provided by Sahagun-Ruiz et al., it is clearly evident that stealth viruses have no distinguishing characteristics identifiable by those skilled in the art. In addition, since Sahagun-Ruiz et al. refer to stealth viruses as "putative", it is apparent that there is doubt in the art as to whether stealth viruses even exist.

The working examples describe pigmentation, auto-fluorescence, particulate and extraneous material, in stealth virus cultures. The only energy source exposed to cells in the working examples is light, see pages 51-52. The discussion of the results appear to indicate that the reduction of pigmentation and movement of cells away from the light source indicates treatment. However, there is no indication that this light treatment reduced viral infection or titers in cell culture or that this treatment would have any effect on an infection within a subject. This working example does not demonstrate any credible utility for the instant method claimed because the energy source applied is anything other than light, see claim 19. With respect to other forms of energy encompassed by the claims, the prior art indicates that exposure of virally infected cells to different energy sources does not affect viruses or induces detrimental effects. Grimaldi et al. (Journal of Environmental Pathology, Toxicology and Oncology. 1997; 16 (2&3): 205-207) teach that exposure of Epstein-Barr virus infected cells to a magnetic field increased the number of cells expressing early antigens of the virus, see the entire reference. Further,

Libertin et al. (Radiation Research. 1994; 140: 91-96) teach electromagnetic field and microwave exposure of the HIV-LTR had no effect, see the abstract, the paragraph bridging pages 93-94 and Figure 5. Therefore, considering the lack of beneficial effects of electromagnetic exposure on cells infected with other viruses, it is determined that the instantly claimed method has no credible utility.

Claims 19-21 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a credible asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shanon Foley whose telephone number is (571) 272-0898. The examiner can normally be reached on M-F 10:00 AM - 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (571) 272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Shanon Foley
Primary Examiner
Art Unit 1648